



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifiers: CMS-10105, CMS-10191, CMS-10525, CMS-10623, and CMS-R-246]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Centers for Medicare & Medicaid Services.

ACTION: Notice.

SUMMARY: The Centers for Medicare & Medicaid Services (CMS) is announcing an opportunity for the public to comment on CMS' intention to collect information from the public. Under the Paperwork Reduction Act of 1995 (the PRA), federal agencies are required to publish notice in the Federal Register concerning each proposed collection of information (including each proposed extension or reinstatement of an existing collection of information) and to allow 60 days for public comment on the proposed action. Interested persons are invited to send comments regarding our burden estimates or any other aspect of this collection of information, including any of the following subjects: (1) the necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

DATES: Comments must be received by [Insert date 60 days after date of publication in the Federal Register].

ADDRESSES: When commenting, please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be submitted in any one of the following ways:

1. Electronically. You may send your comments electronically to <http://www.regulations.gov>. Follow the instructions for "Comment or Submission" or "More Search Options" to find the information collection document(s) that are accepting comments.

2. By regular mail. You may mail written comments to the following address:

CMS, Office of Strategic Operations and Regulatory Affairs

Division of Regulations Development

Attention: Document Identifier/OMB Control Number _____

Room C4-26-05

7500 Security Boulevard

Baltimore, Maryland 21244-1850.

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, you may make your request using one of following:

1. Access CMS' Web Site address at <http://www.cms.hhs.gov/PaperworkReductionActof1995>.
2. E-mail your request, including your address, phone number, OMB number, and CMS document identifier, to Paperwork@cms.hhs.gov.
3. Call the Reports Clearance Office at (410) 786-1326.

FOR FURTHER INFORMATION CONTACT: Reports Clearance Office at (410) 786-1326.

SUPPLEMENTARY INFORMATION:

Contents

This notice sets out a summary of the use and burden associated with the following information collections. More detailed information can be found in each collection's supporting statement and associated materials (see ADDRESSES).

CMS-10105 National Implementation of In-Center Hemodialysis CAHPS Survey

- CMS-10191 Medicare Parts C and D Program Audit Protocols and Data Requests
- CMS-10525 Program of all-Inclusive Care for the Elderly (PACE) Quality Data Entry in CMS Health Plan Monitoring System
- CMS-10623 Testing Experience and Functional Tools Demonstration: Personal Health Record (PHR) User Survey
- CMS-R-246 Medicare Advantage, Medicare Part D, and Medicare Fee-For-Service Consumer Assessment of Healthcare Providers and Systems (CAHPS) Survey

Under the PRA (44 U.S.C. 3501-3520), federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. The term "collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA requires federal agencies to publish a 60-day notice in the Federal Register concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice.

1. Type of Information Collection Request: Revision of a currently approved collection; Title of Information Collection: National Implementation of the In-Center Hemodialysis CAHPS Survey; Use: Data collected in the national implementation of the In-center Hemodialysis Consumer Assessment of Healthcare Providers and Systems (CAHPS) Survey will be used to: (1) provide a source of information from which selected measures can be publicly reported to beneficiaries as a decision aid for dialysis facility selection, (2) aid facilities with their internal quality improvement efforts and external benchmarking with other facilities, (3) provide CMS with information for

monitoring and public reporting purposes, and (4) support the end-stage renal disease value-based purchasing program. Form Number: CMS-10105 (OMB control number: 0938-0926). Frequency: Occasionally; Affected Public: Individuals or households; Number of Respondents: 109,328; Total Annual Responses: 109,328; Total Annual Hours: 59,037. (For policy questions regarding this collection contact Elizabeth Goldstein at 410-786-6665.)

2. Type of Information Collection Request: Revision of a currently approved collection; Title of Information Collection: Medicare Parts C and D Program Audit Protocols and Data Requests; Use: Under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 and implementing regulations at 42 CFR parts 422 and 423, Medicare Part D plan sponsors and Medicare Advantage organizations are required to comply with all Medicare Parts C and D program requirements. In 2010, the explosive growth of these sponsoring organizations forced CMS to develop an audit strategy to ensure we continue to obtain meaningful audit results. As a result, CMS' audit strategy reflected a move to a more targeted, data-driven and risk-based audit approach. We focused on high-risk areas that have the greatest potential for beneficiary harm.

To maximize resources, CMS will focus on assisting the industry to improve their operations to ensure beneficiaries receive access to care. One way to accomplish this is CMS will develop an annual audit strategy which describes how sponsors will be selected for audit and the areas that will be audited. CMS has developed several audit protocols and these are posted to the CMS website each year for use by sponsors to prepare for their audit. Currently CMS utilizes the following 7 protocols to audit sponsor performance: Formulary Administration (FA), Coverage Determinations, Appeals & Grievances (CDAG), Organization Determination, Appeals and Grievances (ODAG), Special Needs Model of Care (SNPMOC) (only administered on organizations who operate SNPs), Compliance Program Effectiveness (CPE), Medication Therapy Management (MTM) and Provider Network Accuracy (PNA). The data collected is detailed in each of these protocols and the exact fields are located in the record layouts, at the

end of each protocol. In addition, questionnaires are distributed as part of our CDAG, ODAG and CPE audits. These questionnaires are also included in this package.

As part of a robust audit process, CMS also requires sponsors who have been audited and found to have deficiencies to undergo a validation audit to ensure correction. The validation audit utilizes the same audit protocols, but only tests the elements where deficiencies were found, as opposed to re-administering the entire audit. Finally, to assist in improving the audit process, CMS sends sponsors a link to a survey (Appendix D) at the end of each audit to complete in order to obtain the sponsors' feedback. The sponsor is not required to complete the survey. Form Number: CMS-10191 (OMB control number: 0938-1000); Frequency: Yearly; Affected Public: Private Sector (business or other for-profit and not-for-profit institutions); Number of Respondents: 40; Total Annual Responses: 40; Total Annual Hours: 13,640. (For policy questions regarding this collection contact Dawn Johnson at 410-786-3159.)

3. Type of Information Collection Request: Revision of a currently approved collection; Title of Information Collection: Program of all-Inclusive Care for the Elderly (PACE) Quality Data Entry in CMS Health Plan Monitoring System; Use: PACE organizations coordinate the care of each participant enrolled in the program based on his or her individual needs with the goal of enabling older individuals to remain in their community. To be eligible to enroll in PACE, an individual must: be 55 or older, live in the service area of a PACE organization (PO), need a nursing home-level of care (as certified by the state in which he or she lives), and be able to live safely in the community with assistance from PACE (42 CFR 460.150(b)).

The PACE program provides comprehensive care whereby an interdisciplinary team of health professionals provides individuals with coordinated care. The overall quality of care is analyzed by information collected and reported to CMS related to specific quality indicators that may cause

potential or actual harm. CMS analyzes the quality data to identify opportunities to improve the quality of care, safety and PACE sustainability and growth.

Previously, quality reporting was identified as Level I or Level II reporting. Level I reporting requirements refer to those data elements that POs regularly report to CMS via the CMS Health Plan Management System (HPMS) PACE monitoring module. (Please see Appendix A for the list of data elements.) POs have been collecting, submitting and reporting data to CMS and State administering agencies (SAA) since 1999.

When analyzing the Level I data, findings may or may not trigger a Quality Improvement (QI) process of analysis (e.g., Plan, Do, Study, Act known as PDSA). Findings may indicate the need for a change in policies, procedures, systems, clinical practice or training. Level II reporting requirements apply specifically to unusual incidents that result in serious adverse participant outcomes, or negative national or regional notoriety related to PACE.

In this PRA package, we are making title changes from Level I and Level II to PACE Quality Data. We are requesting to update and implement previously collected PACE data elements known as Level I and Level II into PACE quality data. Additionally, we are establishing three PACE Quality measures adopted from the National Quality Forum (NQF) and modified for PACE use. These modified PACE quarterly measures are Falls, Falls with Injury, and Pressure Injury Prevalence/Prevention. Currently, the existing Level I and Level II elements have not been tested for reliability or feasibility. By adopting NQF defined reliable data collection process for these elements, certain existing Level I and Level II elements will then officially meet quality measures collection standards. These measures will be used to improve quality of care for participants in PACE. PACE Quality measures will be implemented via the existing HPMS. POs will be educated on data criteria, entry and will report quarterly. Form Number: CMS-10525 (OMB control number:

0938-1264); Frequency: Quarterly and occasionally; Affected Public: Private sector (Business or other for-profits and Not-for-profit institutions); Number of Respondents: 100; Total Annual Responses: 29,500; Total Annual Hours: 211,500. (For policy questions regarding this collection contact Tamika Gladney at 410-786-0648).

4. Type of Information Collection Request: New collection (Request for a new OMB control number); Title of Information Collection: Testing Experience and Functional Tools Demonstration: Personal Health Record (PHR) User Survey; Use: The PHR user survey is important to the TEFT Program Evaluation and understanding the impact of the TEFT PHR on Medicaid CB-LTSS beneficiaries. The TEFT evaluation team's approach includes monitoring state PHR implementation efforts and fielding a follow-up questionnaire to CB-LTSS program participants that asks about their experiences using the PHR. The evaluation seeks to measure the degree to which the PHR is implemented in an accessible manner for Medicaid beneficiaries of CB-LTSS. The survey also is designed to assess the user experience of the PHR, including access and usability, as well as some measures of user satisfaction and perceived impacts of PHR use. Form Number: CMS-10623 (OMB control number: 0938-New); Frequency: Once; Affected Public: Individuals and households; Number of Respondents: 824; Total Annual Responses: 824; Total Annual Hours: 192,113 (For policy questions regarding this collection contact Kerry Lida at 410-786-4826).

5. Type of Information Collection Request: Revision of a currently approved collection; Title of Information Collection: Medicare Advantage, Medicare Part D, and Medicare Fee-For-Service Consumer Assessment of Healthcare Providers and Systems (CAHPS) Survey; Use: The primary purpose of the Medicare consumer assessment of healthcare providers and systems (CAHPS) surveys is to provide information to Medicare beneficiaries to help them make more informed choices among health and prescription drug plans available to them. The surveys also provides data

to help CMS and others monitor the quality and performance of Medicare health and prescription drug plans and identify areas to improve the quality of care and services provided to enrollees of these plans. Form Number: CMS-R-246 (OMB control number: 0938-0732); Frequency: Yearly; Affected Public: Individuals and households; Number of Respondents: 799,650; Total Annual Responses: 799,650; Total Annual Hours: 192,113 (For policy questions regarding this collection contact Sarah Gaillot at 410-786-4637).

Dated: June 8, 2016

William N. Parham, III

Director, Paperwork Reduction Staff

Office of Strategic Operations and Regulatory Affairs

Billing Code: 4120-01-U-P

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